

# In the United States Court of Federal Claims

## OFFICE OF SPECIAL MASTERS

No. 16-0340V

Filed: April 20, 2018

UNPUBLISHED

HILDA ALMANZAR,

Petitioner,

v.

SECRETARY OF HEALTH  
AND HUMAN SERVICES,

Respondent.

Special Processing Unit (SPU) ;  
Entitlement; Ruling on the Record;  
Decision Without a Hearing;  
Causation-In-Fact; Influenza (Flu)  
Vaccine; Shoulder Injury Related to  
Vaccine Administration (SIRVA)

*Maximillian J. Muller, Muller Brazil, LLP, Dresher, PA, for petitioner.*

*Sarah Christina Duncan, U.S. Department of Justice, Washington, DC, for respondent.*

### **RULING ON ENTITLEMENT**<sup>1</sup>

**Dorsey**, Chief Special Master:

On March 16, 2016, Hilda Almanzar (“petitioner”) filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*,<sup>2</sup> (the “Vaccine Act”). Petitioner alleges that she suffered a right shoulder injury related to vaccine administration (“SIRVA”) as a result of an influenza (“flu”) vaccination she received on October 9, 2014. Petition at 1-2. The case was assigned to the Special Processing Unit of the Office of Special Masters. For the reasons discussed herein, the undersigned finds that petitioner is entitled to compensation.

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<sup>1</sup> Because this unpublished ruling contains a reasoned explanation for the action in this case, the undersigned intends to post it on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, the undersigned agrees that the identified material fits within this definition, the undersigned will redact such material from public access.

<sup>2</sup> National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all “§” references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

## **I. Procedural History**

### **a. From Petition filing to Fact Hearing**

On March 16, 2016, Ms. Almanzar filed her petition, medical records and Statement of Completion marked as exhibits 1-4. (ECF Nos. 1-2.) Subsequently, on April 20, 2016, an initial status conference held where additional outstanding medical records were identified. (ECF No. 8.) Those outstanding records and an amended Statement of Completion were filed on June 20, 2016 and October 5-6, 2016. (ECF Nos. 9-10, 15-16.)

On November 7, 2016, respondent filed a status report stating he was interested in pursuing settlement discussions and requested that the deadline for the Rule 4(c) report be suspended. (ECF No. 17). The deadline for respondent to file the Rule 4(c) report was suspended and petitioner was ordered to file a status report in 30 days updating the undersigned on the status of the parties' settlement discussions. (ECF No. 18).

Over the next six months, the parties attempted to informally resolve this matter. On May 8, 2017, petitioner filed a status report stating that the parties had reached an impasse and were requesting a fact hearing. (ECF No. 34). Respondent proposed filing a Rule 4(c) report by June 30, 2017. This request was granted. (ECF No. 35).

On June 30, 2017, respondent filed his Rule 4(c) Report. (ECF No. 36.) Respondent recommended against awarding compensation to petitioner in this case. *Id.* Respondent argued, *inter alia*, that the evidence was insufficient to show a logical sequence of cause and effect or a temporal relationship between vaccination and injury because petitioner did not seek medical attention for her shoulder injury until four months after her vaccination. *Id.* at 7. Respondent argued that the record was unclear regarding the timing of onset of petitioner's injury and as such, petitioner had failed to establish causation-in-fact by a preponderance of the evidence. *Id.*

Thereafter, following a status conference held by the staff attorney managing this case, the undersigned concluded that the case was ripe for a fact hearing. (ECF No. 37.) In preparation for the hearing, petitioner filed additional information requested by respondent in her Rule 4(c) report and another Statement of Completion on August 30, 2017. (ECF No. 39-40.)

### **b. Fact Hearing and Ruling**

A fact hearing was held in Washington, D.C., on December 5, 2017. Ms. Almanzar was the sole witness and she appeared via video-conferencing from New Jersey with her attorney. At the conclusion of the hearing, the undersigned informed the parties that she intended to issue her fact ruling from the bench. The parties consented. The fact ruling, which was memorialized in a written ruling on December 21, 2017, found that the onset of petitioner's symptoms occurred within 48 hours of the

administration of the flu vaccine to Ms. Almanzar. The undersigned also found that Ms. Almanzar had no history of pain, inflammation or dysfunction of her right shoulder prior to her flu vaccine administration, that the pain and reduced range of motion was limited to her right shoulder which is the shoulder in which the vaccine was administered, and that there was no other condition or abnormality that would explain petitioner's symptoms.

The undersigned also found that given the totality of the facts and circumstances set forth in the medical records, other exhibits, and testimony, that there was preponderant evidence of causation establishing that petitioner has proven a clinical course consistent with a SIRVA (shoulder injury related to vaccine administration) claim. The written ruling memorializing these findings was issued on December 20, 2017. (ECF No. 43).

### **c. Procedural History Subsequent to the Fact Hearing and Ruling**

On December 20, 2017, the undersigned filed two articles pertaining to causation of vaccine-related shoulder injuries which were filed as court exhibits. These articles are: B. Atanasoff et al., *Shoulder injury related to vaccine administration (SIRVA)*, 28 Vaccine 8049 (2010), filed as Court Exhibit I, and M. Bodor and E Montalvo, *Vaccination Related Shoulder Dysfunction*, 25 Vaccine 585 (2007), filed as Court Exhibit II. (ECF No. 47.) The parties were given until January 19, 2018, to provide any additional evidence regarding entitlement or any response to the court exhibits. (*Id.*) No further filings were made and the undersigned considers the record as to entitlement closed as of January 19, 2018. (ECF No. 42.) The matter is now ripe for adjudication.

## **II. Factual History**

Ms. Almanzar was a 57-year-old property manager when she received the flu vaccine in her right arm at a Shoprite pharmacy on October 9, 2014. Petitioner's Exhibit ("Pet. Ex.") 1 at 1; Pet. Ex. 3 at 1; Pet. Ex. 5. She had no prior history of shoulder pain or shoulder injury.

On February 11, 2015, approximately four months after vaccination, petitioner presented to Virtua Family Medicine complaining of right arm pain. Pet. Ex. 2 at 1-4. She reported experiencing non-radiating, constant but dull pain in her arm for four months. *Id.* On examination, Ms. Almanzar's right shoulder was tender laterally, her thumb down test was positive, she had signs of impingement, and she had reduced range of motion ("ROM"). *Id.* Her cervical spine exam was normal. *Id.* The assessment was right shoulder tendonitis and acromioclavicular joint pain. *Id.* The physician ordered an x-ray and, after petitioner "insist[ed]," an MRI. *Id.* at 1. Petitioner was prescribed meloxicam and referred to physical therapy ("PT"). *Id.*

An MRI was conducted on February 18, 2015 and showed "[m]ild to moderate supraspinatus and infraspinatus tendinosis with more advanced tendinosis at the junction of the supraspinatus and infraspinatus tendons," and mild subacromial and subdeltoid bursitis. Pet. Ex. 2 at 9. An x-ray taken the same day revealed likely calcific

tendinitis or bursitis, and “[q]uestionable small loose body in the glenohumeral joint.” *Id.* at 11.

On March 19, 2015, Ms. Almanzar presented to orthopedic surgeon Mark Schwartz, M.D. Pet. Ex. 3 at 1. She reported experiencing five months of right shoulder pain and Dr. Schwartz noted, “[s]he attribute[d] this to a flu [shot] in October.” *Id.* Petitioner’s exam showed a painful arc of motion of the right shoulder, as well as a positive impingement sign, and painful resistance testing. *Id.* at 2. Dr. Swartz’s assessment was tendinitis and shoulder calcification, and he administered a subacromial steroid injection. *Id.* at 3.

Ms. Almanzar returned to Dr. Schwartz on April 16, 2015, complaining of continued shoulder pain. Pet. Ex. 3 at 4. The record indicates that Ms. Almanzar had a limited motion despite a “comprehensive course of physiotherapy.” *Id.* On exam, petitioner had a limited ROM, positive impingement signs, and painful resistance testing. *Id.* Dr. Schwartz recommended arthroscopic surgery and possible rotator cuff repair “because of a lack of improvement with conservative treatment.” *Id.*

On May 5, 2015, Ms. Almanzar underwent surgery on her right shoulder, including manipulation, adhesion lysis, rotator cuff repair, subacromial decompression, and acromioplasty. Pet. Ex. 3 at 12-13. Petitioner’s post-operative diagnosis was adhesive capsulitis and a rotator cuff tear. *Id.* at 12.

Petitioner returned for post-operative follow-up visits with Dr. Schwartz on May 7 and May 21, 2015. Pet. Ex. 3 at 6-7. At both visits, Dr. Schwartz noted improved range of motion. *Id.* at 6-7. On June 8, 2015, Ms. Almanzar returned for her one month post-operative visit. *Id.* at 8. Her ROM continued to improve, but she suffered strength deficits. *Id.* at 8.

On June 17, 2015, Ms. Almanzar presented for her first post-surgery PT appointment at NovaCare Rehabilitation. Pet. Ex. 4 at 1. Petitioner reported that her ability to lift and reach and to dress herself was limited, and that she suffered from nightly sleep disturbances. *Id.* Ms. Almanzar rated her pain at 2 out of 10, and 5 out of 10 at its worst. *Id.* The physical therapist noted that petitioner reported “insidious onset of pain starting . . . after 10/9/14 flu vaccine.” *Id.*

Petitioner returned to Dr. Schwartz for a two month post-operative appointment on July 8, 2015. Pet. Ex. 3 at 9. Her range of motion continued to improve, but she still experienced strength deficits. *Id.*

On September 10, 2015, Dr. Schwartz noted that petitioner’s range of motion and strength were improving but that she still had some mild discomfort. Pet. Ex. 3 at 10. Dr. Schwartz administered another steroid injection and instructed her to follow up in a month. *Id.*

Between June 17 and November 11, 2015, Ms. Almanzar attended 38 physical therapy sessions. Pet. Ex. 4. By November 11, 2015, her passive and active range of motion slowly improved. Pet. Ex. 4 at 124. Petitioner reported dressing with minimal difficulty and that she only struggled to lift heavy objects. *Id.* She also noted fewer sleep disturbances and rated her pain at 2 out of 10 at its worst. *Id.*

On November 18, 2015, Ms. Almanzar contacted her physical therapist to report increased pain in her right shoulder. Pet. Ex. 7 at 7. She declined to come into therapy for a reevaluation appointment prior to her appointment with her primary care physician due to concerns with increased pain. *Id.* Petitioner denied any exacerbating incident. *Id.* The following day, Ms. Almanzar returned to Dr. Schwartz and reported “predominantly right-sided neck pain which spreads across her shoulder blade.” Pet. Ex. 9 at 2. A cervical spine exam showed her “shoulder show motion [sic] to lateral rotation and some trigger points posteriorly on the right side.” *Id.* Dr. Schwartz prescribed Skelaxin and referred petitioner to physical therapy for her cervical spine. *Id.*

On December 28, 2015, Ms. Almanzar presented to Orthopedic & Spine Rehabilitation for an evaluation with continued complaints of right shoulder pain and stiffness. Pet. Ex. 8 at 1. She reported that the pain in her right shoulder began suddenly after a flu shot on October 9, 2014. *Id.*

On January 5, 2016, petitioner was discharged from physical therapy at NovaCare Rehabilitation. Pet. Ex. 7 at 9. During her final reevaluation, it was noted that petitioner demonstrated good improvement since her prior reevaluation. *Id.* She had improved range of motion with her shoulder internal rotation which was her primary area of deficit and concern. *Id.*

Petitioner then began physical therapy sessions at Orthopedic & Spine Rehabilitation. Between December 28, 2015 and March 24, 2016, petitioner attended 19 physical therapy sessions with some improvement. Pet. Ex. 8. On April 7, 2016, Ms. Almanzar returned to Dr. Schwartz complaining of increased pain in her shoulder over the preceding few months. Pet. Ex. 9 at 3. Dr. Schwartz noted that petitioner was distressed by the continued pain in her shoulder. *Id.* He administered a steroid injection and prescribed Mobic. *Id.* Dr. Schwartz advised petitioner to follow up in three weeks. *Id.*

Ms. Almanzar filed an affidavit dated May 1, 2017, in which she averred that “[i]mmediately after the vaccination, [she] felt some pain in [her] right shoulder,” and “[o]ver the next two weeks, [she] developed more significant discomfort, pain and range of motion issues . . . .” Pet. Ex. 14 at ¶ 3. She stated that in the injection did not initially “debilitate [her] to the point where [she] had to see a doctor.” *Id.* ¶ 4. Petitioner stated that she tried to schedule an appointment with her family doctor, but she was booked from December 14, 2014 to January 2015. *Id.* ¶ 5. Petitioner averred that she scheduled appointments on January 6 and 26, 2015, both of which were canceled due to snow storms. *Id.* Petitioner stated that she reported the vaccine as the cause of her

shoulder injury at her February 11, 2015 appointment, and that she was “surprised and upset that was not mentioned in the medical records.” *Id.* ¶ 6.

### III. Legal Standard

Because petitioner’s claim predates the inclusion of SIRVA on the Vaccine Injury Table, petitioner must prove her claim by showing that her injury was “caused-in-fact” by the vaccination in question. § 300aa-13(a)(1)(B); § 300aa-11(c)(1)(C)(ii). In such a situation, the presumptions available under the Vaccine Injury Table are inoperative. The burden is on the petitioner to introduce evidence demonstrating that the vaccination actually caused the injury in question. *Althen v. Sec’y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005); *Hines v. Sec’y of Health & Human Servs.*, 940 F.2d 1518, 1525 (Fed. Cir. 1991). The showing of “causation-in-fact” must satisfy the “preponderance of the evidence” standard, the same standard ordinarily used in tort litigation. § 300aa-13(a)(1)(A); see also *Althen*, 418 F.3d at 1279; *Hines*, 940 F.2d at 1525. Under that standard, the petitioner must show that it is “more probable than not” that the vaccination was the cause of the injury. *Althen*, 418 F.3d at 1279.

A petitioner need not show that the vaccination was the sole cause or even the predominant cause of the injury or condition, but must demonstrate that the vaccination was at least a “substantial factor” in causing the condition, and was a “but for” cause. *Shyface v. HHS*, 165 F.3d 1344, 1352 (Fed. Cir. 1999).

Under the leading *Althen* test, petitioner must satisfy three elements. The *Althen* court explained this “causation-in-fact” standard, as follows:

Concisely stated, *Althen*’s burden is to show by preponderant evidence that the vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury. If *Althen* satisfies this burden, she is “entitled to recover unless the [government] shows, also by a preponderance of the evidence, that the injury was in fact caused by factors unrelated to the vaccine.”

*Althen*, 418 F.3d at 1278 (citations omitted). The *Althen* court noted that a petitioner need not necessarily supply evidence from medical literature supporting petitioner’s causation contention, so long as the petitioner supplies the medical opinion of an expert. *Id.* at 1279-80. The court also indicated that, in finding causation, a Program fact-finder may rely upon “circumstantial evidence,” which the court found to be consistent with the “system created by Congress, in which close calls regarding causation are resolved in favor of injured claimants.” *Id.* at 1280.

#### IV. Analysis - Althen Prongs

##### i. A Medical Theory Causally Connecting the Vaccination and Injury

To satisfy the first *Althen* prong, the petitioner must show that the vaccination in question can cause the injury alleged. See *Pafford v. Sec’y of Health & Human Servs.*, 2004 WL 1717359, at \*4 (Fed. Cl. Spec. Mstr. July 16, 2004), *aff’d*, 64 Fed. Cl. 19 (2005), *aff’d*, 451 F.3d 1352 (Fed. Cir. 2006). The petitioner must offer a medical theory which is reputable and reliable. See, e.g., *Pafford v. Sec’y of Health & Human Servs.*, 451 F.3d 1352, 1355 (reputable); *Moberly v. Sec’y of Health & Human Servs.*, 592 F.3d 1315, 1324 (Fed. Cir. 2010) (reliable). The petitioner must prove this prong by preponderant evidence. *Broekelschen v. Sec’y of Health & Human Servs.*, 618 F.3d 1339, 1350 (Fed. Cir. 2010).

##### 1. SIRVA Injury

Effective for petitions filed beginning on March 21, 2017, SIRVA is an injury listed on the Vaccine Injury Table (“Table”). See Vaccine Injury Table: Qualifications and aids to interpretation. 42 C.F.R. § 100.3(c)(10). Although petitioner’s claim was filed before SIRVA was added to the Table, and thus cannot be found to be a SIRVA Table injury, the undersigned’s findings were informed by the Qualifications and Aids to Interpretation for SIRVA criteria used to evaluate such claims. The criteria are as follows:

A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following: (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection; (ii) Pain occurs within the specified time-frame; (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and (iv) No other condition or abnormality is present that would explain the patient’s symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

*Id.*; see also National Vaccine Injury Compensation Program: Revisions to the Vaccine Injury Table, 80 Fed. Reg. 45132, Notice of Proposed Rulemaking, July 29, 2015 (citing Atanasoff S, Ryan T, Lightfoot R, and Johann-Liang R, 2010, *Shoulder injury related to vaccine administration (SIRVA)*, Vaccine 28(51):8049-8052).

##### a. The elements of petitioner’s SIRVA claim

The undersigned’s findings and conclusions are as follows:

**1. Petitioner did not have a history of pain, inflammation or dysfunction of the affected shoulder prior to vaccine intramuscular administration.**

The undersigned reviewed Ms. Almanzar's medical history prior to her influenza vaccination. The medical records demonstrate that Ms. Almanzar did not have a history of pain, inflammation or dysfunction of the affected (right) shoulder prior to vaccination. The records of petitioner's primary care physician and orthopedic surgeon do not reveal a history of prior right shoulder problems. Additionally, petitioner's testimony during the fact hearing supports this finding. Thus, petitioner has satisfied this criterion.

**2. Onset occurred within the specified time frame.**

Based upon the evidence set forth in the medical records, affidavits and petitioner's testimony during the fact hearing, the undersigned held that onset of petitioner's shoulder pain was within 48 hours of the September 30, 2014 flu vaccination, and therefore, is within the Vaccine Table specified time frame of  $\leq 48$  hours. § 13(a)(1)(A) (preponderant standard). See e.g., Pet. Ex. 2 at 1 (petitioner reported that she had experienced right arm pain "since 09/2014 (since flu vac received)"; Pet. Ex. 2 at 104 ("marked discomfort to [right] arm where influenza vacc[ination] administered[.]"); Pet. Ex. at 18 ("[Patient] [complains of] throbbing pain [right] humerus immediately after getting her flu vaccine back in late September. . . [Right] arm pain that started after she received the flu shot[.]"); Pet. Ex. 26 at 1 ("The flu vaccine was injected into my right arm. Later that evening, my arm started to ache.").

The undersigned notes that there is one conflicting piece of evidence, a note by physical therapist, Todd Updike, on June 17, 2015, which states that petitioner had an "insidious onset of pain." See Pet. Ex. 4 at 1. The use of the word 'insidious' implies that the problem developed gradually. However, this entry can be explained by petitioner's affidavit, paragraph three, where she states, "Immediately after the vaccination, I felt some pain in my right shoulder. Over the next two weeks, I developed more significant discomfort, pain and range of motion issues in the shoulder." Pet. Ex. 14 at 1. Thus, the undersigned finds by preponderant evidence, that the onset was immediate, and sudden, as documented by Mr. Harris, gradually worsened and was insidious as documented by Mr. Updike.

Regarding petitioner's delay in seeking treatment until February, 2015, the undersigned found the reasons for the delay as set forth in petitioner's affidavit and as described during her testimony at the fact hearing to be credible and reasonable. Specifically, petitioner described that she tried to schedule an earlier appointment with her primary care physician, Dr. Sapna Jain, but there were no available appointments until January 2015. An appointment that was scheduled for January 6, 2015, was subsequently cancelled due to inclement weather. Another appointment scheduled for January 26, 2015 was also cancelled due to inclement weather. For these reasons, petitioner was unable to see a doctor for her shoulder until February 11, 2015. The undersigned found this delay in seeking treatment to be reasonable given these specific facts and circumstances. Thus, the undersigned finds that petitioner has presented

preponderant evidence that the onset of her shoulder pain occurred immediately after the flu vaccine was administered and that this was within the specified time frame of 48 hours.

**3. Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered.**

As discussed above, Ms. Almanzar received the flu vaccination to her right shoulder and all of her reports of pain, the objective examinations of reduced range of motion, impingement and bursitis, and all of the treatments she received due to these complaints have been limited to her right shoulder.

For the above reasons, the undersigned finds that Ms. Almanzar experienced pain and reduced range of motion limited to the shoulder in which she received the vaccine.

**4. No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).**

The undersigned finds that there are no conditions or abnormalities present that would explain petitioner's right shoulder symptoms.

**i. Logical sequence of cause and effect showing the vaccine was the reason for the injury**

Guided by the criteria for evaluating a Table SIRVA injury, the undersigned finds that Ms. Almanzar has shown, by a preponderance of the evidence, a logical sequence of cause and effect showing that her October 9, 2015 flu vaccine was the reason for her shoulder injury. The SIRVA criteria provides a perfectly logical sequence of cause and effect including (1) no history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection; (ii) Pain occurs within the specified time-frame; (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g. NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy). The undersigned has found, *infra*, that petitioner has satisfied all these requirements and thus has satisfied *Althen* prong two.

Moreover, based on the undersigned's knowledge and experience reviewing a large number of SIRVA claims, petitioner's clinical course is consistent with SIRVA. The undersigned further bases this finding on the previously filed articles, Court Exhibit I (B. Atanasoff et al., *Shoulder injury related to vaccine administration (SIRVA)*, 28

Vaccine 8049 (2010)) and Court Exhibit II (M. Bodor and E Montalvo, Vaccination Related Shoulder Dysfunction, 25 Vaccine 585 (2007)).

ii. **Proximate temporal relationship between vaccination and injury**

“The proximate temporal relationship prong [under *Althen*] requires preponderant proof that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder’s etiology, it is medically acceptable to infer causation-in-fact.” *De Bazan v. Sec’y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). This analysis involves two inquiries: (1) considering the medical basis of the proffered theory, how long after vaccination would onset or worsening of the disease occur; and (2) did onset or worsening of the disease actually occur in the expected timeframe. The first inquiry necessarily intersects with the prong one analysis. See *Langland v. Sec’y of Health & Human Servs.*, 109 Fed. Cl. 421, 443 (2013); *Veryzer v. HHS*, 100 Fed. Cl. 344, 356 (2011).

As discussed above, under the SIRVA criteria, the onset of the symptoms of petitioner’s shoulder injury must begin within 48 hour or less of the vaccination. The undersigned has found that the onset of petitioner’s shoulder injury began within 48 hours of the vaccination, and thus, petitioner has satisfied *Althen* prong two.

**V. Conclusion**

A cause-in-fact injury is established when petitioner demonstrates by a preponderance of the evidence: (1) she received a vaccine set forth on the Vaccine Injury Table; (2) she received the vaccine in the United States; (3) he sustained or had significantly aggravated an illness, disease, disability, or condition caused by the vaccine; and (4) the condition has persisted for more than six months. § 13(a)(1)(A). To satisfy the burden of proving causation in fact, petitioner must establish each of three factors announced by the Federal Circuit in *Althen v. Sec’y of Health & Human Servs.* by preponderant evidence: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a proximate temporal relationship between vaccination and injury. 418 F.3d 1274, 1278 (Fed. Cir. 2005). Proof of medical certainty is not required. *Bunting v. Sec’y of Health & Human Servs.*, 931 F.2d 867, 873 (Fed. Cir. 1991).

**In light of all of the above, and in view of the submitted evidence, including the medical records and the parties’ respective motions, the undersigned finds petitioner entitled to Vaccine Act compensation.**

**IT IS SO ORDERED.**

**s/Nora Beth Dorsey**  
Nora Beth Dorsey  
Chief Special Master